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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/660,288	09/11/2003	Michael Zung	6771USP4	5342

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EXAMINER

ANDERSEN, MICHAEL T

ART UNIT	PAPER NUMBER
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3734

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/01/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

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Office Action Summary

Application No.

10/660,288

Applicant(s)

ZUNG ET AL.

Examiner

M. Thomas Andersen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 November 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 3 and 5-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 3 and 5-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Acknowledgement is made of the response filed 11/21/2006, to the non-final Office action dated 8/24/2006.

Response to Arguments

Applicant's arguments filed 11/21/2006 have been fully considered but they are not persuasive. Applicant has argued 1) that the shaft (or a shaft, per claim 1) does not extend distally from a distal end of the housing (i.e. jaws). Applicant has further argued 2) that distal translation of the shaft is limited because the needle 156 is oriented transverse to the longitudinal axis of the distal portion. Applicant has still further argued 3) that the structure of Yoon precludes the needle from being "movable within the shaft and with respect to the housing" or "extending from the needle actuation handle, through the housing and further through the shaft" as recited in independent claims 1 and 12, respectively.

Before going into the particulars of the "shaft" as relied upon in the last Office action, it should be noted that figure 3 of Yoon clearly shows "a shaft" 16 that extends distally from the distal end of the housing 80 (shown in phantom before extension). This shaft also meets the language of independent claims 1 and 12, thus obviating any argument in regard to shaft 1096.

Nevertheless, in addition to the shaft 16 described above, it remains the examiner's contention that Yoon reads on Applicant's claims as currently written.

In regard to Applicants first argument, as referenced in the last Office action, the examiner relies on the language found at col. 7, lines 25-47.

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"A flexible outer member or sleeve 96 of tubular configuration fits telescopically around rod 84 and is axially movable along the length of the rod between a retracted position where a distal end 98 of the flexible sleeve is proximally spaced from the jaws and an extended position where the distal end of the flexible outer member slides over the jaws. . . [T]he sleeve slides over jaws 80 and 82 causing the jaws to close."

In regard to Applicant's second argument, that distal translation of the shaft is limited because the needle 156 is oriented transverse to the longitudinal axis of the distal portion, the Applicant seems to be relying on position of the needle once it is deployed; i.e. the needle is deployed to a configuration such that it is transverse to the longitudinal axis of the housing and shaft. Such distal translation is not limited before the needle is deployed, i.e. before suturing when the needle is still within the shaft.

In regard to Applicant's third argument, with the needle still within the shaft the structure of Yoon does not preclude the needle from being movable within the shaft. The needle is necessarily within the shaft before it is deployed. At the least, the needle is movable within the furthestmost outer sheath 16.

The previous rejection follows:

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims **1, 3, 5, 8, 11, 12-16** and **19** are rejected under 35 U.S.C. 102(b) as being anticipated by **Yoon**, U.S. Patent No. **5,957,937**. Yoon discloses a suturing device comprising a housing 1080; a shaft 1096 (or 16, figure 3, see phantom drawing of housing 80) extending distally from a distal end of the housing (when the housing is closed by the shaft or sleeve 1096; See col. 7, lines 25-47); a needle 156 (fig. 7) movable within the shaft and with respect to the housing, the needle being attached to a length of suture (See Abstract); and a suture cutting blade 1186 positioned on the housing such that when the needle is withdrawn from the device, the suture can be drawn across the blade to sever the suture.

Fig. 13 shows that the blade is positioned near the distal end of the housing; and also mounted on the inner surface.

Yoon's device is capable of the state wherein the needle and the suture are withdrawn from the proximal end of the housing.

The needle has a distal end and the suture is attached to the distal end of the needle. See col. 14, lines 41-46.

Yoon also discloses what can be considered a needle actuation handle that is movable through the proximal end of the housing 1080; a needle 156 (fig. 7) extending from the needle actuation handle, through the housing and further through the shaft; and a suture carried by the device, wherein a portion of the suture is positioned near the distal end region of the shaft such that the needle pulls the suture proximally to position the suture through tissue (See figures 7 and 12).

Figure 7 shows that the needle pulls the suture through the proximal end of the housing when suturing through tissue takes place.

The housing 1080 defines an opening near the distal end, and the blade is positioned in the opening (See fig. 13).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims **6-7, 9-10, 17-18** and **20** are rejected under 35 U.S.C. 103(a) as being unpatentable over Yoon, as applied to claims 1 and 12 above, in view of **Ogburn, RE 22,857**.

Yoon discloses the invention substantially as claimed except for various locations of the suture-cutting blade. However, *In re Japikse* held that claims that read on the prior art except with regard to the position of a claimed element were held unpatentable if shifting the position of the claimed element would not have modified the operation of the device. 181 F.2d 1019; 86 USPQ 70 (CCPA 1950). Simple relocation of the suture-cutting blade does not modify the operation of the claimed device, but merely relocates the location of drawing the suture across the blade.

Furthermore, Ogburn discloses that it is old and well known in the art to use a stationary suture cutting blade on the housing of a medical suturing device for the purpose of severing the suture after it has been applied to the wound (col. 1, lines 29-

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32; col. 2, lines 11-13; and col. 4, lines 3-10; See also figs. 1-3 and 11-13, reference numerals 51-54). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use a stationary suture cutting blade near the proximal end of the housing, on an outside of the housing, on a finger grip on the housing, or on a movable handle of the device of Yoon, in order to gain the advantage of being able to sever the suture after it has been applied to the wound, as taught by Ogburn.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to M. Thomas Andersen whose telephone number is (571) 272-8024. The examiner can normally be reached on M-F 8AM-4:30PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hayes can be reached on (571) 272-4959. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

M. Thomas Andersen

January 22, 2007



MICHAEL J. HAYES
SUPERVISORY PATENT EXAMINER